



electrolytic fluid), rather than in the context of tissue ablation, prior art references that would not have been reasonably considered by one of ordinary skill in the art of tissue ablation to solve problems specific to tissue ablation (such as, drug delivery needles) were included within the ambit of analogous prior art. Thus, by its affirming the Examiner's definition of the "problem to be solved", the Board misapprehended the second prong of the test used to determine whether a prior art reference is analogous prior art under KSR Intl. vs. Teleflex Inc., 127 S. Ct. 1727 (2007).

Second, in determining whether there is any teaching, suggestion, or motivation to incorporate the porous fluid delivery structure disclosed in VanTassel within the tissue ablation probe disclosed in Edwards, the Examiner simplistically reduced the problem to be solved by the claimed invention as finding an alternative way to include pores in a needle. However, in defining the problem to be solved in this manner, the Examiner completely ignored any contribution that one of ordinary skill in the art would have to make to the prior art in reaching the point of having such problem to begin with.

That is, Edwards solves the problem of generating more efficient ablations by delivering electrolytic fluid from the ablation probe. Appellant's specification poses the problem of uniformly delivering electrolytic fluid to tissue to thereby create a more uniform ablation. To get from the respective "problems to be solved" posed by Edwards or Appellant's specification to the more particular problem of finding an alternative way of including pores in a needle, there would have to be some teaching, suggestion, or motivation to incorporate a porous structure into the Edwards ablation probe in the first place. Such teaching, suggestion, or motivation is simply not found in VanTassel, which merely discloses that a sintered porous structure can be used to non-rapidly

deliver a medicament into tissue. Only after improperly using hindsight reconstruction would there be any teaching, suggestion, or motivation in the prior art to combine Edwards and VanTassel in a manner that would result in the claimed invention. Thus, in affirming the Examiner's definition of the problem in this manner, Appellant believes that the Board misapprehended the TSM test used in determining whether the claims are obvious in view of Edwards and VanTassel.

Appellant would also like to present a new argument supporting the non-obviousness of the claims under the "functionality approach" recently reaffirmed in KSR, which held that the TSM test was not to be applied rigidly, but rather is just a factor in determining whether a claimed invention may be obvious over the prior art. Although the Board noted that Appellant had not demonstrated that the advantages of the claimed invention were not predictable, KSR was decided after Appellant had submitted the Appeal Brief and Reply Brief, and there was no apparent need prior to KSR to demonstrate that the advantages of the claimed invention were "not predictable" under the "functional approach" to the obviousness analysis posed in KSR.

#### VanTassel Not Analogous Prior Art

Appellant believes that the Board erred by defining the problem with which the inventors were concerned much too broadly; that is, by defining the problem as "how to also deliver fluid, specifically electrolytic fluid, to the tissue." (Page 7, lines 7-9 of Decision). By doing this, the problem has been defined too simplistically and has been taken entirely out of context. That is, by defining the problem so broadly, the prior art solutions that address the simplistic problem of delivering fluid to tissue for the most part will not be pertinent to a tissue ablation process. Thus, when defining the problem

with which the present claims are directed to solving, such problem must naturally be defined in the context of a tissue ablation process.

The fact that the specification “recognizes that there is a problem [in] using a separate syringe to inject saline into the tissue to be ablated” and that the specification describes “delivering fluid in one or more of the needles in the apparatus for delivering electrical energy” (Page 7, lines 9-14 of Decision) shows that the problem being solved by the claimed invention is in the context of a tissue ablation process. Thus, the actual problem with which the inventors were concerned, and the problem that the Board should be focusing on when determining whether VanTassel is analogous prior art, is how to deliver fluid through the ablation probe to tissue in a manner that generates a more uniform tissue ablation.

However, by broadly defining the problem as “how to deliver fluid, specifically electrolytic fluid, to the tissue” without consideration of the tissue ablation process, the Board has essentially concluded that any prior art reference, such as VanTassel, that discloses delivering fluid to tissue would have commended itself to the inventors’ attention in considering a problem within the context of a tissue ablation process (see In re Icon Health & Fitness, Inc., 2007 U.S. App. LEXIS 18244 (Fed. Cir. 2007) and MPEP § 2141.01(a)) (“A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” (citations omitted) (emphasis added)). In particular, not every prior art reference that discloses delivering fluid to tissue would have commended itself to one of ordinary skill in the art of tissue ablation.

Indeed, if a problem with which an inventor is concerned could be defined out of context, the Federal Circuit in In re Oetiker, 977 F.2d 1443 (Fed. Cir. 1992) would have decided the case differently. In particular, the claimed invention at issue in In re Oetiker was an improvement in a hose clamp that maintained the preassembly condition of the clamp and disengaged automatically when the clamp was tightened [cite]. The Board relied upon a prior art reference that disclosed a hook and eye fastener for use in garments, reasoning that all hooking problems are analogous (similarly to the Board in this case essentially holding that all fluid delivery problems are analogous) [cite]. The Federal Circuit held that the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned, because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments [cite]. However, if the problem with which inventor was concerned was defined by the Federal Circuit as merely hooking fasteners together outside of the context of hose clamps, the Federal Circuit assuredly would have found that the garment prior art was analogous prior art by virtue of the fact that the garment prior art was directed to hooking fasteners together.

Thus, Appellant believes that the Board should have defined the problem with which the inventors were concerned in the present case to be how to deliver electrolytic fluid through an ablation probe to tissue in a manner that generates a more uniform tissue ablation. In defining the problem in this manner, Appellant believes that the Board would have concluded that VanTassel is not analogous prior art, since VanTassel, which is directed to means for non-rapidly delivering a medicament into

tissue, would not have logically commended itself to an inventor's attention in considering the problem of delivering fluid through an ablation probe to tissue in a manner that generates a more uniform tissue ablation.

#### TSM Test of Obviousness Analysis

Appellant believes that this Board erred in concluding that VanTassel suggests incorporating a sintered porous structure into the Edwards probe, because “the Examiner is merely relying on VanTassel to describe ways of including pores in the needle.” (See page 8, lines 13-14 of Decision). It may be true that VanTassel describes a particular way of including pores in the needle, but there would have to be some teaching, suggestion, or motivation in the first place to include porous structures that uniformly deliver fluid in an ablation probe. No such teaching, suggestion, or motivation is found in Edwards or VanTassel.

In concluding that the claims are obvious over the combination of Edwards and VanTassel based on the fact that VanTassel discloses an alternative way of producing pores in a needle, the Examiner has actually ignored the present inventors' contribution, namely, the recognition of the problem that “saline may be perfused into tissue away from the electrodes, or only locally within a portion of the target region”, and as a result, “the target region may not be uniformly heated and necrosed as desired, possibly requiring multiple treatments to ensure that the target region is successfully necrosed” (see page 2, lines 7-15). Notably, while addressing whether a known problem may support a finding of obviousness, recognition of a previously unaddressed problem may support patentability, in conjunction with the invention addressing the problem. See In re Conover, 49 C.C.P.A. 1205, 1207 (C.C.P.A. 1962) citing Eibel Process Co. v.

Minnesota & Ontario Paper Co., 261 U.S. 45 (1923) (“[A]n essential part of the invention was the understanding of the problem which persisted in the art.”).

The Examiner had also ignored the inventors’ conception of the intermediate solution of seeping electrolytic fluid from an ablation probe to uniformly deliver the fluid to the tissue region, and the intermediate solution of forming the shaft of the ablation probe from a porous structure in the ablation probe to uniformly deliver the electrolytic fluid to the tissue region during the ablation process—solutions not found or suggested by VanTassel.

Thus, by ignoring the inventors’ recognition of the unaddressed problems of non-uniformly delivering electrolytic fluid to a tissue region during an ablation process, and having to perform multiple treatments to ensure that the tissue region is successfully ablated, as well as the intermediate solutions of seeping electrolytic fluid from an ablation probe and forming the ablation probe from a porous structure, the Examiner did not fully appreciate the inventive process that had to take place before determining the manner in which the pores are to be incorporated into the porous structure.

Furthermore, the Examiner had ignored the inventive step that one of ordinary skill in the art would have to make to get from the problem posed in Edwards, i.e., delivering electrolytic fluid through a tissue ablation probe, to the Examiner’s defined problem of coming up with an alternative way of delivering electrolytic fluid through a porous structure. Again, there would have to be some suggestion that it would be desirable to use a porous structure in the Edwards ablation probe before the problem posed by the Examiner arises.

Appellant also requests that the Board, in defining the problem to be solved, not benefit from impermissible hindsight vision afforded by the claimed invention. In particular:

Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (M.P.E.P. §2142) (emphasis added).

Without the aid of Appellant's disclosure, there is simply no basis for simplistically describing the problem for the TSM test as finding alternative ways of including pores in a needle. Edwards merely discloses the need for an ablation device with infusion capabilities to improve the resulting tissue ablation (see col. 3, lines 2-9), and VanTassel merely discloses the need to microinject controlled amounts of a therapeutic agent without substantial loss of the therapeutic agent and without substantial damage to tissue (see col. 2, lines 24-32). There is no suggestion in VanTassel to modify the perfusion capability of ablation devices to improve tissue ablation. Given Edwards' problem statement of improving tissue ablation using an ablation device with infusion capabilities, there is no apparent solution in VanTassel to solve this problem without first looking to Appellant's specification.

Thus, considering the actual problem posed by the inventors (or any problem posed in Edwards), there is simply no teaching, suggestion, or motivation in the prior art to incorporate the sintered porous structure disclosed in VanTassel in the probe disclosed in Edwards.

Functional Approach of Obviousness Analysis

The Supreme Court has recently addressed the issue of obviousness in KSR Intl. vs. Teleflex Inc., 127 S. Ct. 1727 (2007), holding that the “teaching, suggestion, or motivation” (TSM) test, which was rigidly applied by the Federal Circuit in an attempt to resolve the issue of obviousness with more uniformity and consistency, was inconsistent with the expansive and flexible approach provided in Graham.

In illustrating the application of the “functional approach” that should be taken when addressing the issue of obviousness, the Supreme Court cited cases that were decided after Graham. For example, in United States v. Adams, 383 U.S. 39, 40 (1966), the Supreme Court recognized “that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result . . . (KSR at page 1740). Citing Sakraida v. AG Pro, Inc., 425 U.S. 273 (1976), the Supreme Court further noted that “[w]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” (Id.).

In the present case, to the extent that the incorporation of the sintered porous structure disclosed in VanTassel can be considered a substitution of the fluid distribution pores in the shaft of the Edwards probe, such substitution would not yield a predictable result. In particular, based on VanTassel’s disclosure that a sintered porous structure can be used to microinject a medicament into tissue while preventing the rapid transfer of the medicament (see col. 2, lines 24-32), the incorporation of the sintered porous structure disclosed in VanTassel into the Edwards probe would yield

unpredictable results—i.e., the uniform delivery of electrolytic fluid into tissue to produce a larger and more efficient tissue ablation, which is not discussed in VanTassel or any other prior art reference cited by the Examiner. The results of incorporating the sintered porous structure of VanTassel into the Edwards probe are only “predictable” after reviewing Appellant’s specification, which as previously discussed, the Board cannot do.

The incorporation of a porous structure into the Edwards probe is also not an arrangement of old elements with each performing the same function it had been known to perform, since the function of the porous structure disclosed in VanHassel is the non-rapid microinjection of a medicament into tissue (see col. 2, lines 18-32), whereas the function of the porous structure in the arrangement hypothesized by the Examiner is the uniform delivery of electrolytic fluid into tissue.

Thus, it is respectfully submitted that, when using the “functional approach” set forth in KSR, the claims are not obvious over the combination of Edwards and VanTassel.

Respectfully submitted,

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